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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10.067,660	02-04-2002	Surendra K. Gupta	4307-0102P	8659

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EXAMINER
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LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/29/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/067,660	GUPTA, SURENDRA K.
	Examiner Louise N. Leary	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-35 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-27 and 29-35 is/are rejected.
- 7) Claim(s) 28 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                         | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 | 6) <input type="checkbox"/> Other: _____                                    |

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1. Claims 1-35 are pending in this application.
2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite due to the lack of a correlation step between "monitoring the progress of fat loss in a patient during a weight loss program" and "a color indication of the presence in said body fluid of B-hydroxybutyrate, optionally together with acetoacetate and/or acetone".

Claim 1 is also indefinite because the metes and bounds intended for the phrase "optionally together with acetoacetate and/or acetone" have not been defined in the instant claim limitations. It is unclear if acetoacetate and/or acetone are present in the body fluid.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 and 29-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ouyang et al (5,902,731).

Ouyang et al disclose a test strip method based on tetrazolium dye precursors for measuring the concentration of beta-hydroxybutyrate (beta-HB) in a biological fluid. Regarding using the "method for monitoring the progress of fat loss in a patient during a weight loss program", Ouyang et al disclose (i) adipose tissue releases stored fatty acids into the circulatory system to be metabolized, (ii) if insufficient amounts of carbohydrates are present in the body due to dieting the fat consumption and fatty acid production can increase to potentially harmful levels and (iii) "when excessive fatty acid is used to supply a body's energy demand, then large quantities of acetoacetate, acetone, and beta-hydroxybutyrate are produced." Ouyang et al further disclose "these intermediates are referred to as ketone bodies, and the condition is known as ketoacidosis." See column 1, lines 1-68. Ouyang et al disclose "a particularly preferred strip comprises

- a) a support layer,
- b) on the support layer, a test pad having a coating that comprises
  - i) a dehydrogenase enzyme that has specificity for the analyte,
  - ii) nicotinamide adenine dinucleotide (NAD) or a NAD derivative,
  - iii) a tetrazolium dye precursor, and
  - iv) a diaphorase enzyme or an analog thereof, and
- c) on the test pad, a bibulous top layer that is coated with a nitrite salt." See column 3, lines 10-21.

Ouyang et al specifically disclose a method wherein beta-hydroxybutyrate is that analyte and beta-hydroxybutyrate dehydrogenase is the enzyme on the test strip. See column 6, lines 5-68, column 7, lines 1-18, and column 8, lines 3-22. With respect to the origin of beta-HBD as described in instant claims 5, 13, 21 and 35, Ouyang et al disclose using a hydroxybutyrate dehydrogenase from *Pseudomonas* sp. Note column 6, lines 34-35. In addition, Ouyang et al disclose using ..."either diaphorase, such as lipoic dehydrogenase, ferredoxin-NADP reductase, lipoamide dehydrogenase, or by a synthetic analog, such as phenazine methosulfate (PMS) or Meldola Blue." See column 4, lines 46-51. Ouyang et al disclose using each of the tetrazolium precursor dye compounds in instant claims 7, 15, and 23. Thus, Ouyang et al disclose the invention claimed except for stating the "beta-HBD is an enzyme that is not inhibited by chloride ions".

However, with respect to the instant limitation the "beta-HBD is an enzyme that is not inhibited by chloride ions", it is noted that the Ouyang et al disclosure addresses this inherent property because Ouyang et al disclose using beta-HBD enzymes identical to enzymes in the invention claimed. As a result, the Ouyang et al reference anticipates or renders obvious the claimed invention.

The burden of proof is on applicants to show patentably distinct differences between the Ouyang et al test strip method and the present invention.

4. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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5. The Lipton et al (US 4,348,205) and Ouyang et al (US 6,420,128) references have been cited to further show the state of this invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY  
PRIMARY EXAMINER

July 26, 2002